

REMARKS

This responds to the Office Action mailed on March 20, 2007.

Claims 1, 20, 32, 35-37, and 59 are amended. Claims 6 and 7 are canceled. Claims 76-103 are added. Claims 71-75 previously were canceled without prejudice or disclaimer. As a result, claims 1-5, 8-70, and 76-103 are now pending in this patent application. Applicant respectfully submits that the amendments to the claims are fully supported by the specification and no new matter has been added.

Double Patenting Rejection

Claims 1, 2, 5, 6, and 8-10 were provisionally rejected for non-statutory obviousness-type double patenting over claims 1-9, 13, and 14 of co-pending U.S. Patent Application Publication No. 2004/0167393. When the claims are otherwise indicated to be allowable, Applicant will consider filing a Terminal Disclaimer in compliance with 37 C.F.R. 1.321(b)(iv) to obviate these rejections.

§102 Rejection of the Claims

1. Claims 1, 6, 8, 17, 59, and 62 were rejected under 35 U.S.C. § 102(b) for anticipation by Foley et al. (U.S. Patent No. 6,226,548). For at least the following reasons, Applicant respectfully traverses this rejection.

As an initial note, claim 6 has been canceled, thereby rendering the rejection thereof moot. Applicant cannot find in Foley et al. each and every recitation of claims 1, 6, 8, 17, 59, and 62. For instance, as amended, Applicant cannot find in Foley et al.:

- “an imagable fiducial locator head that is locatable by an imaging system, the head being at least semispherical; [and] a conical receptacle that is sized and shaped for engaging a locator instrument of a positioning system, the receptacle integrated with the imagable fiducial locator head and configured to permit access to a center of the imagable fiducial locator head”, as recited in claim 1, as amended; and
- “driving directly into a bone of a patient a fiducial marker device including both an at least semispherical imagable locator head and an integral conical receptacle sized and shaped for mating to an instrument detectable by a positioning system and configured

to permit access to a center of the imagable fiducial locator head”, as recited in claim 59, as amended.

Applicant cannot find in Foley et al. an at least semispherical imagable fiducial locator head. The Office Action cites to Figs. 7 and 7A of Foley et al., but it appears that Figs. 7 and 7A show a generally cylindrical screw head. Additionally, Applicant can find no mention of the screw head of Foley et al. including a conical receptacle configured to permit access to a center of the imagable fiducial locator head. Therefore, Applicant respectfully requests withdrawal of the rejection of claims 1 and 59.

Additionally, dependent claims 8, and 17 depend from independent claim 1, and dependent claim 62 depends from independent claim 59. Accordingly, each of these claims incorporates the features of claims 1 and 59, respectively. These dependent claims are accordingly believed to be patentable for the reasons stated herein with respect to claims 1 and 59. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable. Thus, Applicant respectfully requests reconsideration and withdrawal of this rejection and allowance of these claims.

For at least these reasons, Applicant believes claims 1, 8, 17, 59, and 62 to be patentable over Foley et al. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 1, 8, 17, 59, and 62.

2. Claims 1, 2, 6, 17, and 59 were rejected under 35 U.S.C. § 102(e) for anticipation by Mittelstadt (U.S. Patent No. 6,430,434). For at least the following reasons, Applicant respectfully traverses this rejection.

As an initial note, claim 6 has been canceled, thereby rendering the rejection thereof moot. Applicant cannot find in Mittelstadt each and every recitation of claims 1, 2, 17, and 59. For instance, Applicant cannot find in Mittelstadt:

- “an imagable fiducial locator head that is locatable by an imaging system, the head being at least semispherical; [and] a conical receptacle that is sized and shaped for engaging a locator instrument of a positioning system, the receptacle integrated with

the imagable fiducial locator head and configured to permit access to a center of the imagable fiducial locator head”, as recited in claim 1, as amended; and

- “driving directly into a bone of a patient a fiducial marker device including both an at least semispherical imagable locator head and an integral conical receptacle sized and shaped for mating to an instrument detectable by a positioning system and configured to permit access to a center of the imagable fiducial locator head”, as recited in claim 59, as amended.

Applicant cannot find in Mittelstadt an at least semispherical imagable fiducial locator head. The Office Action cites to Fig. 7 of Mittelstadt, but it appears that Fig. 1 shows a generally cylindrical marker. Additionally, Applicant can find no mention of the screw head of Mittelstadt including a receptacle configured to permit access to a center of the imagable fiducial locator head. Instead, Mittelstadt states that “[a] conical locating feature 25 is found at the top end of proximal bone marker 22”. (See Mittelstadt at col. 6, lines 17-18.) Referring to Fig. 1 of Mittelstadt, it appears that the locating feature 25 is in a top end of the marker 22 and does not permit access to a center of the imagable fiducial locator head. Therefore, Applicant respectfully withdrawal of the rejection of claims 1 and 59.

Additionally, dependent claims 2, and 17 depend from independent claim 1. Accordingly, each of these claims incorporates the features of claim 1. These dependent claims are accordingly believed to be patentable for the reasons stated herein with respect to claim 1. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable. Thus, Applicant respectfully requests reconsideration and withdrawal of this rejection and allowance of these claims.

For at least these reasons, Applicant believes claims 1, 2, 17, and 59 to be patentable over Mittelstadt. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 17, and 59.

3. Claims 1, 3, 4, 6, 7, 12, 23, 24, 59, 61, 63, and 65-68, were rejected under 35 U.S.C. § 102(e) for anticipation by Hunter et al. (U.S. Patent No. 6,499,488). For at least the following reasons, Applicant respectfully traverses this rejection.

As an initial note, claims 6 and 7 have been canceled, thereby rendering the rejection thereof moot. Applicant cannot find in Hunter et al. each and every recitation of claims 1, 3, 4, 12, 23, 24, 59, 61, 63, and 65-68. For instance, Applicant cannot find in Hunter et al.:

- “an imagable fiducial locator head that is locatable by an imaging system, the head being at least semispherical; [and] a conical receptacle that is sized and shaped for engaging a locator instrument of a positioning system, the receptacle integrated with the imagable fiducial locator head and configured to permit access to a center of the imagable fiducial locator head”, as recited in claim 1, as amended; and
- “driving directly into a bone of a patient a fiducial marker device including both an at least semispherical imagable locator head and an integral conical receptacle sized and shaped for mating to an instrument detectable by a positioning system and configured to permit access to a center of the imagable fiducial locator head”, as recited in claim 59, as amended.

Applicant cannot find in Hunter et al. an at least semispherical imagable fiducial locator head. Moreover, the Office Action fails to point to such a structure in Hunter et al., instead citing to Figs. 1A and 1B and contending at page 5 that Hunter et al. includes “a faceted cylindrical housing that can be fixedly attached or integrated with the bone screw 18.” Additionally, Applicant can find no mention of Hunter et al. including a conical receptacle configured to permit access to a center of the imagable fiducial locator head. Instead, Hunter et al. appears to discuss “an opening 29 opposite keyed opening 27, for receiving sensor 28.” (See Hunter et al. at col. 5, lines 59-60.) Therefore, Applicant respectfully requests withdrawal of the rejection of claims 1 and 59.

Additionally, dependent claims 3, 4, 12, 23, and 24 depend from independent claim 1, and dependent claims 61, 63, and 65-68 depend from independent claim 59. Accordingly, each of these claims incorporates the features of claims 1 and 59, respectively. These dependent claims are accordingly believed to be patentable for the reasons stated herein with respect to claims 1 and 59. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable. Thus, Applicant respectfully requests reconsideration and withdrawal of this rejection and allowance of these claims.

For at least these reasons, Applicant believes claims 1, 3, 4, 12, 23, 24, 59, 61, 63, and 65-68 to be patentable over Hunter et al. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 1, 3, 4, 12, 23, 24, 59, 61, 63, and 65-68.

§103 Rejection of the Claims

1. Claims 1-5, 9, 13-21, 32-35, 41-48, 59-61, and 67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Allen (U.S. Patent No. 5,397,329) in view Vilsmeier (U.S. Patent No. 6,351,659). Applicant respectfully traverses this rejection.

Applicant respectfully submits that the proposed combination of Allen and Vilsmeier would not have been obvious to a person with ordinary skill in the art, since it does not meet the requirements for obviousness set forth in *KSR International Co. v. Teleflex Inc.*, 550 U. S. ____ (2007). For instance, Applicant submits that the proposed combination would not have been obvious because the proposed combination would be inoperable.

The Office Action at page 6 states that “[w]hile Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument.” Allen states that:

[t]he fiducial implant 10 also has means 16 for receiving force so the anchor 14 can be fixedly secured to the body. Where anchor 14 is a screw, preferably an indentation 16 in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench with the associated polygonal recess has more symmetrical integrity than the cross shaped receptor site for a phillips screw driver or a single groove receptor site for a standard screw driver.

(See Allen at col. 7, lines 53-61.) Allen goes on to state that “[f]orce is then applied to the portion of the rod extending out of the trocar until the implant 10 is embedded into the bone.”

(See Allen at col. 8, lines 5-7.) The Office Action then contends at page 7 that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker”. However, Applicant submits that modifying the indentation 16 of Allen with “a funnel configuration” would render the Allen implant inoperable. For instance, by modifying the Allen implant with “a funnel

configuration”, as proposed by the Office Action, Applicant submits that the indentation 16 would appear to no longer function to “receive force” for embedding the Allen implant into the bone as it would appear to no longer include a faceted polygonal (or other rotational-tool-receiving) shape. Therefore, Applicant submits that the Allen implant, modified as proposed by the Office Action, would be unable to be embedded in bone and would be inoperable. Therefore, Applicant respectfully submits that the proposed combination would not have been obvious to a person with ordinary skill in the art. Accordingly, Applicant respectfully submits that claims 1, 32, and 59 are patentable over Allen and Vilsmeier.

Dependent claims 2-5, 9, and 13-21 depend from independent claim 1, dependent claims 33-35 and 41-48 depend from independent claim 32, and dependent claims 60, 61, and 67 depend from independent claim 59. Accordingly, claims 2-5, 9, 13-21, 33-35, 41-48, 60, 61, and 67 incorporate the features of claims 1, 32, and 59, respectively. These dependent claims are accordingly believed to be patentable for at least the reasons stated herein. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

Therefore, for at least these reasons, Applicant respectfully submits that no *prima facie* case of obviousness presently exists and requests that the § 103 rejection of claims 1-5, 9, 13-21, 32-35, 41-48, 59-61, and 67 be reconsidered and withdrawn.

2-4. Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley et al. in view of Zinreich et al. (U.S. Patent No. 5,368,030). Claims 23, 40, 50, and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Allen in view Vilsmeier and further in view of Bulstra et al. (U.S. Patent No. 6,102,914). Claims 31 and 58 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Allen in view Vilsmeier, further in view of Franck et al. (U.S. Patent No. 6,273,896).

Applicant respectfully traverses these three rejections on the grounds that no *prima facie* case of obviousness presently exists with respect to such claims at least because not all of the claim recitations are taught or suggested by the proposed combinations. Each of claims 10, 23, and 31 depends from claim 1 and incorporates the subject matter of claim 1 therein, and each of claims 40, 50, 51, and 58 depends from claim 32 and incorporates the subject matter of claim 32

therein. Therefore, Applicant submits that claims 10, 23, 31, 40, 50, 51, and 58 are patentable over the cited references based upon at least their dependence from one of claims 1 and 32, each of which are believed to be in condition for allowance for at least the reasons stated above. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections of these claims.

Allowable Subject Matter

Claims 11, 22, 25-30, 36-39, 49, 52-57, 64, 69, and 70 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant gratefully acknowledges the allowability of claims 11, 22, 25-30, 36-39, 49, 52-57, 64, 69, and 70.

Applicant has rewritten claim 26 in independent form as new claim 76. New claims 77-80 depend from claim 76 and track original claims 27-30. Because claims 26-30 were indicated as allowable, Applicant respectfully submits that new claims 76-80 are in condition for allowance.

Also, Applicant has rewritten claim 37 in independent form as new claim 91. New claims 92 and 93 depend from claim 91 and track original claims 28 and 39. Because claims 37-39 were indicated as allowable, Applicant respectfully submits that new claims 91-93 are in condition for allowance.

Additionally, Applicant has rewritten claims 22, 36, 64, 69, and 70 as new claims 81, 88, 94, 98, and 101, respectively. Because claims 22, 36, 64, 69, and 70 were indicated as allowable, Applicant respectfully submits that new claims 81, 88, 94, 98, and 101 and claims dependent therefrom are in condition for allowance.

Reservation of Rights

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any

of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any canceled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3275 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

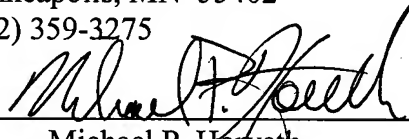
Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 20th day of June 2007.

Name

Signature